REMARKS

Restriction Requirement Under 35 USC §121

Applicants affirm their election of Group II, claims 8-15. Applicants reserve the right to file divisional applications directed to the non-elected subject matter and the subject matter of the canceled claims and any other patentable subject matter disclosed in the specification.

Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 8-15 as being indefinite stating that "substantially reversible point mutation" is not a positive characterization of a cell composition and relates more to a process. The Examiner suggests that Applicants should recite a component in reference to the language. The Examiner adds that the term "substantially" is a relative term which renders the claim indefinite. The Examiner further adds that the term "expressible" connotes indefiniteness in that the cell may not express said gene and relates more to the ability of a cell rather than a positive component of a cell.

Applicants have amended the claim to remove the word "substantially", and, consistent with the Examiner's suggestion, have added the words "of a gene", thereby reciting a component of the claimed cells. Applicants believe that the foregoing amendments do not limit the scope of the claims, but are simply for the purpose of more particularly pointing out and distinctly claiming the invention.

Applicants respectfully submit that the term "expressible" is not indefinite and disagree with the Examiner's suggestion to change this word to "expressed". It is common knowledge that many genes in cells are regulated such that they are sometimes expressed and other times are not expressed. Such regulation may be the result of many factors, such as, for example, metabolism and cell signaling mechanisms. Applicants submit that using the term "expressed" would unfairly limit the scope of the claim.

The Examiner has further rejected claims 10, 12 and 15 as being indefinite in the designation of the different bacterial strains. Applicants respectfully traverse the rejection. As is stated in the specification (page 21, lines 1-15), each of the claimed cell strains has been deposited with the American Type Culture Collection (ATCC) under the Budapest Treaty and a deposit number has been assigned. Moreover, the

specification generally describes the methods of making the cells of the invention, which are based upon the bacterial cell strains used in the known Ames assay (see page 19, line 23 to page 20, line 23).

Based upon the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 8-15 35 U.S.C. §112, second paragraph.

Rejection of Claims Under 35 U.S.C. § 102

The Examiner has rejected claims 8-10 and 12-15 under 35 U.S.C. § 102(b) as being anticipated by WO 94/13831 (Larossa et al.). Applicants respectfully traverse the rejection.

Applicants submit that the organism(s) disclosed in Larossa is not the same as that claimed by Applicants with respect to Applicant's claimed bacterial strains having mutations on the histidine or β-lactamase genes (mutations on the tyrptophan gene are not considered here because, as indicated by the Examiner in her comments to the rejection under §103 below, Larossa does not disclose mutations in the tryptophan gene). Larossa discloses a system wherein a reporter gene is linked to a stress inducible promoter. Applicants invention does not involve the linking of a reporter gene to a promoter. Moreover, the promoter that is specifically described as used in Larossa is one that is inducible by stress. Applicants' do not transform cells with a stress inducible promoter.

Larossa describes cells that are very limited in structure to those that have a stress inducible promoter *operably linked* (or operably connected) to a reporter gene (see page 1, lines 7-12). The terms "operably linked" and "stress inducible promoter" are defined within a relatively limited scope (see page 11, lines 25-27 and page 13, lines 22-24). These terms are inconsistent with Applicants' invention.

Specifically, the Examiner references Larossa, for example, at page 58, Example 17, as disclosing cells which express the lux(CDABE) gene and the transformation of such cells by mutating the histidine codon. Applicants submit that Example 17 is very different than described by the Examiner in that it only describes a *his* promoter linked to the *lux* gene. This example illustrates how different the cells described in Larossa are from those claimed by Applicants. Applicants submit that the cells in Example 17 only detect activity of the *his* promoter.

The Examiner further makes reference to the use in Larossa of serine hydroxamate (at page 59, lines 12 to page 60, line 15) as describing a *ser* mutation. Applicants understand the Examiner's comments as referring to cells claimed by Applicant having a mutation on the active site serine codon of the β-lactamase gene. Applicants, submit that the use of serine hydroxamate as a reagent in Larossa is not relevant to a mutation on the β-lactamase gene.

Based upon the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims claims 8-10 and 12-15 under 35 U.S.C. § 102(b).

Rejection of Claims Under 35 U.S.C. § 103

The Examiner has rejected claims 11 under 35 U.S.C. § 103(a) as being anticipated by WO 94/13831 (Larossa et al.) in view of Green et al (1976). Applicants respectfully traverse the rejection. For the reasons submitted above regarding the rejection under §102, Applicants submit that Larossa does not disclose the bacterial strains claimed by Applicants having mutations on *his* or *ser*. Therefore, it is not possible that one skilled in the art would be motivated to combine Larossa with Green to reach Applicants' invention.

Based upon the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. § 103(a).

Based on the foregoing, it is believed that the application is in condition for allowance. Such prompt and favorable action is requested.

Respectfully submitted,

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